

DOCKET NO. 130694.02801
PATENT

SERIAL NO. 10/576,481
FILED: May 15, 2008

REMARKS

Status of the Claims

Claims 1-5, 10, 13, 39, 48-50 and 52 are in the application.

Claim 39 has been withdrawn from consideration.

Claims 1-5, 10, 13, 48-50 and 52 were rejected.

By way of this amendment, claims 1, 2 and 13 have been amended, claim 39 has been canceled and new claim 58 has been added.

Upon entry of this amendment, claims 1-5, 10, 13, 48-50, 52 and 58 will be pending.

Summary of the Amendment

Claims 1, 2 and 13 have been amended to more clearly set forth the subject matter of the invention. As amended, each of claims 1, 2 and 13 refer to the uniquely targeting siRNA nucleotide sequence for the target mRNA as lacking complete complementarity to the target mRNA. Support for these amendments is found throughout the specification such as on page 7.

Claim 39 has been canceled as directed at a non-elected invention.

New claim 57 corresponds to claim 13 but is dependent on claim 2 rather than claim 1. Support for new claim 57 is found throughout the specification

No new matter has been added.

Priority

The Office alleges that the claim to benefit of a prior filed application under 35 U.S.C. § 119(e) is not proper because the prior filed application (U.S. Provisional Application No. 60/513,489), allegedly fails to provide adequate support or enablement as required under 35 U.S.C. § 112, first paragraph. Applicants respectfully disagree.

The '489 provides adequate written description support such that one of skill in the art reading the '489 application could immediately envisage the claimed invention and recognize

that Applicants were in possession of the instantly claimed invention at the time the '489 application was filed.

While the exact language of the claims is not used in the '489 application, it is well settled that there is no requirement that the claim language appear *ipsis verbis*. The claimed method is clearly disclosed in the '489 application and one skilled in the art would conclude that Applicants were in possession of the claimed invention at the time the '489 application was filed.

Accordingly, the present application is entitled to priority under 35 U.S.C. § 119(e) and the effective filing date of the present application should be at least the filing date of the '489 application, which is October 22, 2003. In view of the foregoing, Applicants respectfully request that the Office declare that the priority claim is proper.

Claim Rejections under 35 U.S.C. § 102

Liu, et al.

Claims 1-5, 10, 13, 48-50 and 52 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Liu *et al.* (U.S. Publication No. 2004/0091926 A1).

As noted above, Applicants maintain that the claims are entitled to the priority date of October 22, 2003. In view of the priority date, Liu et al. is not prior art. Nevertheless, even if the priority date is not acknowledged, the claims herein are patentable in view of Liu et al.

Independent claims 1 and 2 have been amended to recite that the

the siRNA nucleotide sequence lacks complete
complementarity to the target mRNA sequence.

Accordingly, each claim contains this limitation which distinguishes the claimed invention over the teachings in Liu *et al.*, which discloses siRNA with siRNA nucleotide sequences that have complete complementarity to the target mRNA sequence for a target mRNA molecule.

Claims 1-5, 10, 13, 48-50 and 52 are not anticipated by Liu *et al.* Applicants respectfully request that the rejection of claims 1-5, 10, 13, 48-50 and 52 under 35 U.S.C. § 102(e) as allegedly being anticipated by Liu *et al.* be withdrawn.

Elbashir et al.

Claims 1-5, 13, and 48-50 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Elbashir *et al.* (Methods, 2002, 26:199-213).

Independent claims 1 and 2 have been amended to recite that the

the siRNA nucleotide sequence lacks complete
complementarity to the target mRNA sequence.

Accordingly, each claim contains this limitation which distinguishes the claimed invention over the teachings in Elbashir *et al.*, which discloses siRNA with siRNA nucleotide sequences that have complete complementarity to the target mRNA sequence for a target mRNA molecule.

Claims 1-5, 13 and 48-50 are not anticipated by Elbashir *et al.* Applicants respectfully request that the rejection of claims 1-5, 13 and 48-50 under 35 U.S.C. § 102(b) as allegedly being anticipated by Elbashir *et al.* be withdrawn.

Claim Rejections under 35 U.S.C. § 103

Claims 1-5, 10, 13, 48-50 and 52 stand rejected under 35 U.S.C. § 103(a) allegedly being unpatentable over Elbashir *et al.* in view of Tuschl *et al.* (WO 03/099298), Martinez *et al.* (Cell, 2002, 110:563-574) and Ureta-Vidal *et al.* (Nature Reviews Genetics, 2003, 4:251-262).

Elbashir *et al.*, which discloses siRNA with siRNA nucleotide sequences that have complete complementarity to the target mRNA sequence for a target mRNA molecule.

Tuschl *et al.* discloses that the antisense strand of the siRNA sequence is preferable 100% complementary to the target mRNA sequence and that the target mRNA cleavage occurs at a position corresponding to between nucleotides 10 and 11 of the antisense siRNA sequence.

Martinez *et al.* disclose the RISC-dependent target mRNA cleavage occurs at a position corresponding to between nucleotides 10 and 11 of the antisense siRNA sequence.

Ureta-Vidal *et al.* disclose genomic, mRNA and protein sequence databases.

Independent claims 1 and 2 have been amended to recite that the

the siRNA nucleotide sequence lacks complete
complementarity to the target mRNA sequence.

Accordingly, each claim contains this limitation. Each claim additionally contains the limitations that siRNA nucleotide sequence consists of

18-25 nucleotides including a nucleotide sequence that has 11 consecutive nucleotides, including the third nucleotide from the siRNA nucleotide sequence's 5' end, that are complementary to an 11 nucleotide sequence that occurs on the target mRNA molecule.

The combination of references neither teaches nor suggests that siRNA sequences having incomplete complementarity with the target mRNA can be identified, designed and synthesized provided they have 11 consecutive nucleotides including the nucleotide at position 3 complementary with the target mRNA. The claimed invention provides specific requirements for siRNA sequences that lack complete complementarity with the target mRNA which are not disclosed and could not be gleaned from the combination of references. Elbashir teaches complete complementarity. Tuschl suggests complete complementarity is preferred but not required. Tuschl and Martinez disclose the observation regarding cleavage sites which says nothing regarding the need for 11 consecutive nucleotides including the nucleotide at position 3 complementary with the target mRNA.

In view of the differences between the claimed subject matter and the combination of Elbashir *et al*, Tuschl *et al*, Martinez *et al*. and Ureta-Vidal *et al*. one skilled in the art would not conclude that the claimed invention is obvious. Claims 1-5, 10, 13, 48-50 and 52 stand rejected under 35 U.S.C. § 103(a) allegedly being unpatentable over Elbashir *et al* in view of Tuschl *et al*. (WO 03/099298), Martinez *et al*. (*Cell*, 2002, 110:563-574) and Ureta-Vidal *et al*. (*Nature Reviews Genetics*, 2003, 4:251-262). Claims 1-5, 10, 13, 48-50 and 52 are patentable over the combination of Elbashir *et al*, Tuschl *et al*, Martinez *et al*. and Ureta-Vidal *et al*. Applicants respectfully request that the rejection of claims 1-5, 10, 13, 48-50 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Elbashir *et al* in view of Tuschl *et al*, Martinez *et al*. and Ureta-Vidal *et al*. be withdrawn.

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Conclusion

Claims 1-5, 10, 13, 48-50, 52 and 58 are in condition for allowance. A notice of allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

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